

## **REMARKS**

Claims 35-58 have been rejected under 35 USC 112, first paragraph, as failing to comply with the enabling requirements. Claim 35 has been rejected because it contains the limitations “recess”, “recess depending means”, “stoma covering means” and “means for defining said recess”. According to the examiner, these limitations are not present in the specification.

Applicant respectfully points out that the specification and drawings clearly disclose components of the invention that support each of the limitations in question, although the specification may not use the precise terminology employed by the claims.

As is clearly taught by the specification, and illustrated by Figures 2 and 3, membrane A' functions to “cover and seal the stoma” and the interior of cap B' defines a recess within which membrane A' is situated. Hence, member A' is taught as being a “stoma covering means” and cap B' is taught as defining a recess and thus can accurately be described as a “recess defining means” or a “means for defining a recess.”

Those limitations are present in the specification. There is no requirement, and the examiner points to none, that the claims only use the same terminology as is used in the specification. However, applicant has replaced paragraph 5 of page 9 with a paragraph that employs the identical language as used in the claims.

Further, applicant has substituted “chamber” for “recess” in claims 35, 38, 39, 44 and 48 to correspond with the language in the specification and corrected the spelling of “removably” in claim 51.

Claim 46 has been rejected under 35 USC 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter applicant regards as the invention because it is unclear what method/process applicant is intending to claim.

Claim 46 does not claim a method or process. Claim 46 adds an element, an external pressurization device, to claim 35.

Although applicant believes that claim 46 is proper as presented, it has been amended to eliminate “for use” to avoid any ambiguity.

Claims 35-39, 41, 44 and 45-56 have been rejected under 35 USC 102(b) as anticipated by Bar-Shalom (WO 90/07311A1). As emphasized by the title of the invention, and taught in the specification, applicant’s invention is an “external” seal, that is “designed to be mounted externally and to exert a low pressure...across the entire face of the stoma.”

In that way, the seal can adapt to a variety of stoma sizes and shapes and accommodate irregularities in the stoma and, at the same time, permit gas to escape from the stoma to reduce internal pressure build up in the intestine.

In order to highlight this structural difference between applicant’s device and those of the prior art, including the Bar-Shalom reference, applicant’s claims explicitly require that the stoma covering means be “situated externally to the body, over the stoma”. That is clearly not the case with Bar-Shalom, which utilizes an internally received means of sealing the stoma.

In Bar-Shalom, the closure member (16) includes a stopper member (17) that is inserted into the intestinal opening in the closed position of the closure member. Further, the inner open end of the container 14 is fastened to a ring member 18 forming part of an

expandable retaining member. The disclosure explains that when the mounting ring 18 has been adhered to the skin surface 12 around the stoma 13, a unit comprising the collapsed retaining member 16, with the stopper member 17 received in the ring member 18, is inserted into the stoma or intestinal opening 13, as shown in Figure 1.

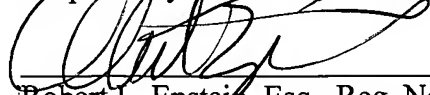
In all embodiments disclosed by the reference there is at least a portion of the device that is received within the stoma. In no embodiment is the "stoma covering means, situated externally to the body, over the stoma, within the recess defining means", as required by the claim.

Further, the claim as amended requires that (a) the recess defining means (cap B') and the stoma covering means (membrane A') define a chamber, (b) that the chamber be situated over the stoma covering means and (c) that the chamber be pressurizable to press the stoma covering means against the stoma.

The Bar-Shalom device does not have a pressurizable chamber and does not operate by pressurization of the means that covers the stoma.

Accordingly, the Bar-Shalom reference cannot be said to anticipate applicant's claims.

Respectfully submitted,



Robert L. Epstein, Esq., Reg. No. 26451

EPSTEIN DRANGEL

BAZERMAN & JAMES, LLP

Attorneys for Applicant

60 East 42<sup>nd</sup> Street, Suite 820

New York, New York 10165

Tel. No.: (212) 292-5390

Fax. No.: (212) 292-5391